|                           | Utech                              |
|---------------------------|------------------------------------|
| Name :                    |                                    |
| Roll No.:                 | A Spring Of Exercising and Explana |
| Invigilator's Signature : |                                    |

# CS/M.PHARM/SEM-1/MPT-115(1)/2011-12 2011

# **QUALITY OF ASSURANCE-I**

Time Allotted: 3 Hours Full Marks: 70

The figures in the margin indicate full marks.

Candidates are required to give their answers in their own words as far as practicable.

#### GROUP - A

### ( Multiple Choice Type Questions )

1. Choose the correct alternatives for any ten of the following:

 $10 \times 1 = 10$ 

- i) For the preparation of purified water I.P. the microbiological specification of the potable water used is not more than
  - a) 500 cfu/ml
  - b) 200 cfu/ml
  - c) 100 cfu/ml
  - d) none of these.
- ii) Diluted disinfectants shall bear the label
  - a) use within
- b) use before
- c) use after
- d) none of these.

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| iii)  | The  | recommended frequen                       | icy of | f periodic monitoring of  |  |
|-------|--|---|--------|---------------------------|--|
|       | particulate in air is  |   |        |                           |  |
|       | a)   | three monthly                             | b)     | daily                     |  |
|       | c)   | six monthly                               | d)     | yearly.                   |  |
| iv)   |  | pressure differentials                    | in a   | septic room should be     |  |
|       | a)   | yearly                                    | b)     | daily                     |  |
|       | c)   | six monthly                               | d)     | three monthly.            |  |
| v)    | In case of metered dose inhaler where the products on clean components are exposed, the area shall be supplied with filtered air of grade. |   |        |                           |  |
|       | a)   | C   | b)     | A                         |  |
|       | c)   | В   | d)     | D.                        |  |
| vi)   | Cetı   | rimide is ty                              | pe of  | surface active agent.     |  |
|       | a)   | anionic                                   |        |                           |  |
|       | b)   | nonionic                                  |        |                           |  |
|       | c)   | cationic.                                 |        |                           |  |
| vii)  | i) Chlorhexidine acetate is used in<br>formulation.  |   |        | l in                      |  |
|       | a)   | Mouthwash                                 | b)     | Shampoo                   |  |
|       | c)   | Toothpaste                                | d)     | Cold cream.               |  |
| viii) |  | implication of purchas<br>be evaluated by | ed ma  | aterials on finished good |  |
|       | a)   | the organization                          | b)     | storekeeper               |  |
|       | c)   | drugs inspector                           | d)     | none of these.            |  |



- ix) The minimum area reqired for basic installations of ointments and lotion section is
  - a) 50 sq m
- b) 20 sq m
- c) 100 sq m
- d) none of these.
- x) The word C in CGMP represents
  - a) Cancelled
- b) Conditional
- c) Current
- d) None of these.
- xi) Which one of the following steps is not used in lyophilization?
  - a) Freezing the product solution
  - b) Sealing of the container
  - c) Drying
  - d) Application of positive pressure.

#### GROUP - B

# (Short Answer Type Questions)

Answer any three of the following.

 $3 \times 5 = 15$ 

- 2. Give the test to be undertaken for the evaluation of safety of liquid shampoo preparations.
- 3. Describe the benefits of SOPs to an organization.
- 4. Describe the responsibilities of head of quality control and head of production department.
- 5. Mention at least five check points for self-inspection of sterile production related to 'Premises'.
- 6. Write a note on waste and scrap disposal procedures.



#### (Long Answer Type Questions)

Answer any three of the following.



- 7. a) Give the basic requirements of a good dentrifice. Write in brief about the agents that may be used to attain the desirable characteristics of a good dentrifice. Discuss their advantages and disadvantages.
  - b) What are the uses of mouthwashes? Write in brief about the formulation of such preparations in reality. Give the components and specific requirements of such agents in actual situation. (2+5)+(2+3+3)
- 8. Describe the general requirements for quality management system and requirements for products. Elaborate quality management system approach.

  9 + 6
- 9. a) Describe the salient points that have to be considered for designing a layout for factory premises.
  - b) Describe HVAC system.

10 + 5

- 10. a) Describe the factors to be considered for installation of equipment.
  - b) Write a note on cleaning and maintenance of equipment. 9+6
- 11. Describe in detail about in process quality control test of tablet dosage form.

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